

REMARKS

Applicant is amending the claims as set forth above to better define the invention. A petition to extend time for one month is enclosed. If any fees are due, please charge them to Bracewell & Giuliani LLP deposit account 50-0259. Applicant respectfully traverses the rejection of the claims and respectfully requests reconsideration.

The amendments to claim 1 essentially comprise the deletion of option iii), and the addition of the subject matter of claims 5, 9, 16 and 17. We have used the term "RFID" in place of the term "RF tag" used in claim 5. However, it is clear from paragraph 51 of the application that it is well known that RF tag devices are also known as RFID devices.

The examiner indicated that Porat, et al. and Noren, et al. were considered to fall in the scope of option iii) of previous claim 1 because it was the examiner's position that both of these documents disclosed devices capable of monitoring the function of a heart valve. Whilst we do not agree with the examiner's interpretation, we note that present claim 1 has had option iii) deleted therefrom. Thus, present claim 1 is more tightly focused to heart valves, and we believe that neither Porat, et al. nor Noren, et al. can anticipate present claim 1 because both of these citations fail to disclose that a heart valve or a device which assists in the functioning of a heart valve might be contemplated. In fact, both of these documents fail to even suggest that a heart valve or a device that assists in the functioning of a heart valve might be contemplated.

In our view, the only citation put forward by the examiner which discloses a heart valve having a telemetric sensing capability is Villafana. However, in contrast to present claim 1, Villafana does not disclose that a piezoelectric sensor comprising a polymetric active sensing area which senses blood pressure of the patient might be provided, as required in amended claim

1. Furthermore, Vallafana does not disclose the provision of telemetric communication means comprising an RFID device. Therefore, present claim 1 is not anticipated by Villafana.

The device defined by present claim 1 provides a practical and useful medical device which is economic to produce and provides highly clinically relevant blood pressure measures taken deep within the patient's heart. The blood pressure data can be used to provide information on the status of the heart valve. Villafana does not disclose or even suggest that a heart valve might be equipped with a pressure sensor. Rather, Villafana states that a sensor "capable of detecting the motion of the occluder" or "a blood flow sensor" might be used (column 2, lines 52-56).

Furthermore, none of the prior art cited by the examiner, including Villafana, discloses or even suggests that a piezoelectric sensor comprising a polymeric active sensing area might be used to sense the blood pressure of the patient. In that regard, we note that Porat, et la. discloses the use of a PVDF piezoelectric layer (column 18, example 2) as an acoustic sensor and not a blood pressure sensor. Furthermore, as noted above, Porat, et al. is not concerned with heart valves, and thus contains no suggestion whatsoever that a heart valve or a device which assists in the functioning the patient's heart valve might be equipped with a sensor which senses the blood pressure of the patient. An advantage associated with the use of a piezoelectric sensor comprising a polymeric active sensing area in combination with the telemetry technology utilized in the present invention is that a flexible sensor can be produced which can be bent to conform to the contours encountered at the point of use.

Also, we believe that it is non-obvious to utilize an RFID device in a heart valve or a device which assists in the functioning of a heart valve for telemetry purposes. Whilst RFID

devices *per se* were previously known, in the main these devices have been used for position monitoring. The present invention provides the teaching that RFID devices may be coupled to one or more sensors, and that these devices may be implanted in the heart of a patient for medical measurement purposes. Furthermore, in the medical context the use of RFID devices provides further advantages. The present inventors have realized that RFIDs can be identified and interrogated uniquely even when located in the body with other similar devices. This is a property not shared by other radio frequency technologies. A further advantage is that the RFID device can store highly relevant information, such as the dates of implantation, the model of the device, etc. This information can be read by a remote device, and thus this information is effectively carried by the patient. Therefore, a separate recording system, which is subject to error or inadvertent deletion, is not required. When combined with the other features described in present claim 1, a practical and economic medical device pertaining to heart valve is provided which enables highly relevant clinical information to be conveniently obtained. For at least these reasons, we submit that present claim 1 is not obvious in view of any of the prior art cited in the office action.

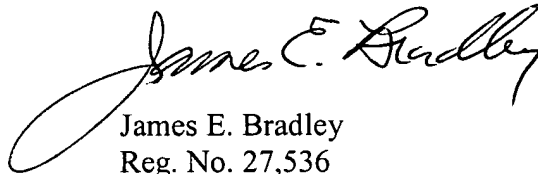
Claim 24 also requires a piezoelectric sensor comprising a polymeric active sensing area which senses blood pressure of the patient. It also requires that the telemetric communication means comprise an RFID device. For the reasons discussed above, we submit that claim 24 is also allowable.

We have also provided a new independent claim 31, which calls for the ability to sense acoustic signals in addition to the blood pressure of the patient. The comments made above in respect of present claim 1 apply to new claim 31. Furthermore, none of the prior art cited by the examiner discloses or even suggests an acoustic sensor might be usefully incorporated in a heart

valve or a device that assists in the functioning of a heart valve. The acoustic sensor is particularly useful when provided in combination with a blood pressure sensor. In addition to providing important information relating to the patient's heart, the acoustic sensor can also provide information pertaining to the operation of the heart valve. For example, leakage through the valves can be detected. For at least these reasons, we believe that claim 31 is not obvious in view of any of the prior art cited by the examiner.

We respectfully submit that the claims are in condition for allowance and respectfully request reconsideration.

Respectfully submitted,

A handwritten signature in black ink, reading "James E. Bradley". The signature is fluid and cursive, with a large, sweeping initial "J".

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